RadioMed Corporation
9 Linnell Circle
Billerica, MA 01821-3902

510k Summary

1. Sponsor Name

RadioMed Corporation
9 Linnell Circle
Billerica, Massachusetts 01821-3902

Telephone: (978) 663-7400 voice
(978) 663-7771 fax

Contact Individual: John Schwamb

2. Device Name

Proprietary Name:	RadioMed™ Source
Common/Usual Name:	Brachytherapy Radionuclide Source
Classification Name:	Brachytherapy Radionuclide

3. Identification of Predicate or Legally Marketed Device

The predicate devices for the RadioMed™ Source are:
Theragenics Pd-103 Seed K874787
Medi-Physics Rapid Strand™ K940632
Ir-192 Wires from Amersham International – Preammendments device

4. Device Description

The RadioMed™ source utilizes Pd-103 as the radionuclide for brachytherapy. The RadioMed™ Source exists in the form of a coiled rhodium wire. The rhodium matrix also provides the radiopacity of the device. The RadioMed™ Source is a naturally sealed source in the form of a wire.

The RadioMed™ Source is packaged non-sterile, single use, and is intended to be sterilized by the end user in accordance with a validated sterilization process. Sterilization is accomplished by exposure to steam autoclave.

The RadioMed™ Source will be manufactured, labeled and packaged under GMP controls. Upon completion of the manufacturing and assembly process the device will be inspected to assure compliance to

7 Performance Testing

Summary of standards achieved:

FDA QSR 21 CFR Part 820 Good Manufacturing Practices
ISO 10993-1 1992 (E) Biological Evaluation of Medical Devices
ANSI N43.6-1997: Classification of sealed radioactive sources
ANSI N44.1-1973 Integrity and Test Specifications for selected Brachytherapy Sources
ANSI N44.2-1973 Leak testing radioactive brachytherapy sources
ISO 9978: 1992(E) "Radiation protection – Sealed radioactive sources – Leakage test methods".
AAMI Standard 11134-1994 Recommended practice for Steam Autoclave

The "performance" of the RadioMed™ source is subdivided into four categories

1. Radiation Energy
2. Source Strength Measurement: Calibration and Calibration Accuracy
3. Dose Comparison
4. Sealed Source Testing

specifications. The devices will be tested in accordance with Standard Operating Procedures.

The sources are delivered in the same manner as brachytherapy seeds currently on the market, i.e. a 17 or 18-gauge needle and stylet.

5. Intended Use

The RadioMed™ Source with activities from 0.1 to 5.0 mCi per centimeter length is indicated for temporary or permanent interstitial implantation or surface application to treat selected localized tumors. They can be used as either primary treatment or as treatment for residual disease after excision of primary or recurrent tumors. The RadioMed™ Source may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia, or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate and other accessible tumors are commonly treated.

6. Comparison of Technological Characteristics

The design of each of the predicates and the RadioMed™ Source is a sealed source from which to deliver a therapeutic dosage of radioactive energy. The predicate devices use a sealed source in a "can" configuration, often referred to as a seed. The RadioMed™ Source is a sealed source in the form of a wire. The RadioMed source, like Ir-192 wires, is linear. In contrast, the Theragenics Seed and the I-125 Seeds that are inside of the Rapid Strand™ are designed to emulate point sources.

The energy emitted for the RadioMed™ Source and the Theragenics ^{103}Pd Seed is exactly the same: 20-23 keV x-rays.

The materials that make up the components of the predicates and the RadioMed™ Source are both similar and different. The shells for the predicate devices and the RadioMed™ Source are different. Both predicate seeds use titanium. The RadioMed Source uses rhodium. The radionuclide for the predicate Theragenics ^{103}Pd seed is Palladium - 103 which is the same as the RadioMed™ Source. The marker in each of the predicate devices is lead, while that in the RadioMed Source is rhodium.

The delivery of the predicates and the RadioMed™ Source is through a 17 or 18-gauge needle and stylet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2000

John Schwamb
Quality Manager
RadioMed Corporation
9 Linnell Circle
Billerica, MA 01821

Re: K001070
RadioMed™ Source
Dated: August 4, 2000
Received: August 7, 2000
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Mr. Schwamb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K001070

Device Name: RadioMed™ Source

Indications For Use:

The RadioMed™ Source with activities from 0.1 to 5.0mCi per centimeter is indicated for temporary or permanent interstitial implantation or surface application to treat selected localized tumors. They can be used either as primary treatment (such as for prostate cancer or unresectable tumors) or as treatment for residual disease after excision of primary or recurrent tumors. The Pd-103 sources may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia, or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate and other accessible tumors are commonly treated.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Lepay
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001070